Complete Summary

GUIDELINE TITLE

Vasomotor symptoms. In: Menopause and osteoporosis update 2009.

BIBLIOGRAPHIC SOURCE(S)

Vasomotor symptoms. In: Menopause and osteoporosis update 2009. J Obstet Gynaecol Can 2009 Jan;31(1 Suppl 1):S9-10. [26 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Desindes S, Belisle S, Graves G. Menopause and age-related concerns. In: Canadian consensus conference on menopause, 2006 update. J Obstet Gynaecol Can 2006 Feb;28(2 Suppl 1):S21-32. [97 references]

Graves G, Blake J. Specific medical considerations. In: Canadian consensus conference on menopause, 2006 update. J Obstet Gynaecol Can 2006 Feb;28(2 Suppl 1):S75-80. [68 references]

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- December 16, 2008 - Antiepileptic drugs: The U.S. Food and Drug Administration (FDA) has completed its analysis of reports of suicidality (suicidal behavior or ideation [thoughts]) from placebo-controlled clinical trials of drugs used to treat epilepsy, psychiatric disorders, and other conditions. Based on the outcome of this review, FDA is requiring that all manufacturers of drugs in this class include a Warning in their labeling and develop a Medication Guide to be provided to patients prescribed these drugs to inform them of the risks of suicidal thoughts or actions. FDA expects that the increased risk of suicidality is shared by all antiepileptic drugs and anticipates that the class labeling change will be applied broadly.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Menopause and menopause-related vasomotor symptoms

GUIDELINE CATEGORY

Management
Prevention
Risk Assessment
Treatment

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Obstetrics and Gynecology
Psychiatry

INTENDED USERS

Advanced Practice Nurses
Health Care Providers
Nurses
Physician Assistants
Physicians
Psychologists/Non-physician Behavioral Health Clinicians

GUIDELINE OBJECTIVE(S)

To provide updated guidelines for health care providers on the management of menopause in asymptomatic healthy women as well as in women presenting with vasomotor symptoms or with urogenital, mood, or memory concerns, and on considerations related to cardiovascular disease, breast cancer, and bone health, including the diagnosis and clinical management of postmenopausal osteoporosis

TARGET POPULATION

- Menopause in asymptomatic healthy women

- Menopause in women presenting with vasomotor symptoms, urogenital, sexual, and mood and memory concerns and specific medical considerations and cardiovascular and cancer issues

INTERVENTIONS AND PRACTICES CONSIDERED

1. Lifestyle modifications
    - Reducing core body temperature
    - Regular exercise
    - Weight management
    - Smoking cessation
    - Avoidance of known triggers
2. Hormone therapy (HT)
    - Estrogen alone
    - Estrogen and progestogen therapy (EPT)
    - Progestins alone
    - Low dose oral contraceptives
3. Non-hormonal therapies (antidepressants, gabapentin, clonidine, bellergal)
4. Investigation of any postmenopausal bleeding

MAJOR OUTCOMES CONSIDERED

- Symptom relief
- Side effects of therapy

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

MEDLINE was searched up to October 1, 2008, and the Cochrane databases up to issue 1 of 2008 with the use of a controlled vocabulary and appropriate key words. Research-design filters for systematic reviews, randomized and controlled clinical trials, and observational studies were applied to all PubMed searches. Results were limited to publication years 2002 to 2008; there were no language restrictions. Additional information was sought in BMJ Clinical Evidence, in guidelines collections, and from the Web sites of major obstetric and gynaecologic associations worldwide.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Quality of Evidence Assessment*

I: Evidence obtained from at least one properly randomized controlled trial.

II-1: Evidence from well-designed controlled trials without randomization.

II-2: Evidence from well-designed cohort (prospective or retrospective) or case-control studies, preferably from more than one centre or research group.

II-3: Evidence from comparisons between times or places with or without the intervention. Dramatic results from uncontrolled experiments (such as the results of treatment with penicillin in the 1940s) could also be included in this category.

III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

* Adapted from the Evaluation of Evidence criteria described in: Woolf SH, Battista RN, Angerson GM, Logan AG, Eel W. Canadian Task Force on Preventive Health Care. New grades for recommendations from the Canadian Task Force on Preventive Health Care. Can Med Assoc J 2003;169(3):207-8.

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

The authors critically reviewed the evidence and developed the recommendations according to the methodology and consensus development process of the Journal of Obstetrics and Gynaecology Canada.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Classification of Recommendations*

A. There is good evidence to recommend the clinical preventive action

B. There is fair evidence to recommend the clinical preventive action

C. The existing evidence is conflicting and does not allow to make a recommendation for or against use of the clinical preventive action; however, other factors may influence decision-making

D. There is fair evidence to recommend against the clinical preventive action

E. There is good evidence to recommend against the clinical preventive action

L. There is insufficient evidence (in quantity or quality) to make a recommendation; however, other factors may influence decision-making

*Adapted from the Classification of Recommendations criteria described in: Woolf SH, Battista RN, Angerson GM, Logan AG, Eel W. Canadian Task Force on Preventive Health Care. New grades for recommendations from the Canadian Task Force on Preventive Health Care. Can Med Assoc J 2003;169(3):207-8.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Not stated

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not applicable

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The grades of recommendations (A-E and L) and levels of evidence (I, II-1, II-2, II-3, and III) are defined at the end of the "Major Recommendations" field.

1. Lifestyle modifications, including reducing core body temperature, regular exercise, weight management, smoking cessation, and avoidance of known triggers such as hot drinks and alcohol may be recommended to reduce mild vasomotor symptoms. **(IC)**
2. Health care providers should offer hormone therapy (HT) (estrogen alone or estrogen and progestogen therapy [EPT]) as the most effective therapy for the medical management of menopausal symptoms. **(IA)**
3. Progestins alone or low-dose oral contraceptives can be offered as alternatives for the relief of menopausal symptoms during the menopausal transition. **(IA)**
4. Nonhormonal prescription therapies, including treatment with certain antidepressant agents, gabapentin, clonidine, and bellergal, may afford some relief from hot flashes but have their own side effects. These alternatives can be considered when HT is contraindicated or not desired. **(IB)**

5. There is limited evidence of benefit for most complementary and alternative approaches to the management of hot flashes. Without good evidence for effectiveness, and in the face of minimal data on safety, these approaches should be advised with caution. Women should be advised that, until January 2004, most natural health products were introduced into Canada as "food products" and did not fall under the regulatory requirements for pharmaceutical products. As such, most have not been rigorously tested for the treatment of moderate to severe hot flashes, and many lack evidence of efficacy and safety. **(IB)**
6. Any unexpected vaginal bleeding that occurs after 12 months of amenorrhea is considered postmenopausal bleeding and should be investigated. **(IA)**
7. HT should be offered to women with premature ovarian failure or early menopause **(IA)**, and it can be recommended until the age of natural menopause. **(IIIC)**
8. Estrogen therapy can be offered to women who have undergone surgical menopause for the treatment of endometriosis. **(IA)**

Definitions:

Quality of Evidence Assessment*

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*The quality of evidence reported in these guidelines has been adapted from the Evaluation of Evidence criteria described in the Canadian Task Force on Preventive Health Care.***

Recommendations included in these guidelines have been adapted from the Classification of Recommendations criteria described in the Canadian Task Force on Preventive Health Care.*

***Woolf SH, Battista RN, Angerson GM, Logan AG, Eel W. Canadian Task Force on Preventive Health Care. New grades for recommendations from the Canadian Task Force on Preventive Health Care. Can Med Assoc J 2003;169(3):207-8.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate management of menopause in women providing relief from vasomotor symptoms

POTENTIAL HARMS

Side effects of treatment

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

This document reflects emerging clinical and scientific advances as of the date issued and is subject to change. The information should not be construed as dictating an exclusive course of treatment or procedure to be followed. Local institutions can dictate amendments to these opinions. They should be well documented if modified at the local level. None of these contents may be reproduced in any form without prior written permission of the Society of Obstetricians and Gynaecologists of Canada (SOGC).

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2006 Feb (revised 2009 Jan)

GUIDELINE DEVELOPER(S)

Society of Obstetricians and Gynaecologists of Canada - Medical Specialty Society

SOURCE(S) OF FUNDING

Society of Obstetricians and Gynaecologists of Canada

GUIDELINE COMMITTEE

Not stated

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

The following conflicts of interest have been disclosed by the authors.

Dr Reid: Speaker or consultant to Wyeth, Bayer, Organon, Proctor and Gamble, Novo Nordisk; advisory boards: Paladin, Wyeth; research support: Organon, Bayer.

Dr Blake: Speaker or consultant to Wyeth, Merck, Glaxo Smith Kline, Bayer; advisory boards: Bayer, Wyeth and Lilly, Novo Nordisk.

Dr Abramson: Speaker or consultant to Abbott, Astra Zeneca, Boehringer Ingelheim, Bristol Myer Squibb, Dupont, Eli Lilly, Lifespeak, Norvartis, Fournier, Merck Frosst, Pfizer, Servier, Schering, Sanofi-Aventis; advisory boards: Astra Zeneca, Boehringer-Ingelheim, Novartis, Pfizer, Sanofi-Aventis; research support: Astra Zeneca, Boehringer Ingelheim, Merck.

Dr Khan: Speaker or consultant to Amgen, Merck, Lilly, Novartis, Servier, Proctor and Gamble; research support: Merck, Lilly, Novartis, Alliance for Better Bone Health.

Dr Senikas: None declared.

Dr Fortier: Speaker or consultant to Proctor and Gamble, Merck; advisory boards: Amgen, Bayer, Novo Nordisk, Novartis, GlaxoSmith Kline, Lilly, Paladin; research support: Wyeth, Sanofi.

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Graves G, Blake J. Specific medical considerations. In: Canadian consensus conference on menopause, 2006 update. J Obstet Gynaecol Can 2006 Feb;28(2 Suppl 1):S75-80. [68 references]

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the Society of Obstetricians and Gynaecologists of Canada Web site.

Print copies: Available from the Society of Obstetricians and Gynaecologists of Canada, La société des obstétriciens et gynécologues du Canada (SOGC) 780 promenade Echo Drive Ottawa, ON K1S 5R7 (Canada); Phone: 1-800-561-2416

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI Institute on April 30, 2009. The information was verified by the guideline developer on May 21, 2009.

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